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10/058,820	01/28/2002	Jonathan S. Bogan	0399.2025-002	2441

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EXAMINER

RIGGINS, PATRICK S

ART UNIT PAPER NUMBER

1636

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/058,820

**Applicant(s)**

BOGAN ET AL.

**Examiner**

Patrick S. Riggins

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 22-24 and 32-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21, 25-31, 54, 56 and 57 is/are rejected.
- 7) ☒ Claim(s) 55 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/8/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

10/8/04

### **DETAILED ACTION**

1. Receipt is acknowledged of an amendment, filed 10/8/2004, in which several claims were amended (claims 1, 8, 12-15, 54 & 56). Claims 1-57 are pending in the instant action, with claims 21-24 & 32-53 withdrawn from consideration as being directed to nonelected inventions.
2. Any rejection of record not addressed herein is withdrawn. This action is not final as there are new rejections made herein that were not necessitated by applicants' amendment of the claims in the response filed 10/8/2004.

### ***Information Disclosure Statement***

3. Receipt is acknowledged of an information disclosure statement (IDS) filed on 10/8/2004. The signed and initialed PTO Form 1449 for this IDS has been mailed along with the instant action.

### ***Oath/Declaration***

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 1-21, 25-31, and 56-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 is vague and indefinite in that there is no clear and positive prior antecedent basis in the claims for newly added steps (d), (e) and (f). This situation appears to result from the fact that steps (d), (e) and (f) currently refer back to steps as recited in the original claims. It would be remedial to amend step (d) to refer to the cells sorted in step (c), step (e) to refer to the cells expanded in step (d) and step (f) to refer to the cells sorted in step (e). **This is a new rejection necessitated by applicants' amendment of the claims in the response filed 10/8/2004.**

8. Claim 1 is additionally vague and indefinite because step (e) recites sorting of the cells that have been expanded, but there is no basis for this sorting. Are the cells again stimulated with insulin prior to this additional sorting step? In this case inserting an additional step reciting stimulation with insulin would be remedial. Or are the cells merely re-sorted as an additional measure of ensuring a more pure population of cells? In this case, it would be remedial to clearly state that the cells were re-sorted to ensure greater purity of the sorted populations. **This is a new rejection necessitated by applicants' amendment of the claims in the response filed 10/8/2004.**

9. Claims 6 and 56 are vague and indefinite because to repeat the sorting and expansion steps one must first stimulate with insulin. It would be remedial to include stimulation with insulin in the additional steps recited. **This is a new rejection.**

10. Claim 15 is vague and indefinite in that there is no clear and positive prior antecedent basis for the term "the population of cells" recited in step (e) of the amended claim. It is

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recognized that “a population of cells is identified in step (a), however this population is apparently disrupted in step (d) where individual cells are isolated. This would seem to destroy the population in favor of a variety of clonal cells. In this regard the claim is indefinite because the cloning of cells in step (d) is contrary to the remaining steps (e)-(h). It seems that these steps are intended for different methods, not for the same method. Additionally, it would seem that an insulin stimulation step is necessary prior to step (h). **This is a new rejection.**

11. Claim 25 is vague and indefinite because multiple expression libraries are referred to without clearly identifying which library is the intended. The “expression library of line 3 of step (a) lack antecedent basis because this library is different from the library recited in line 1 of step (a) as the line 3 library is the library from which the line 1 library is derived. To replace “the expression library” in line 3 of step (a) with --an expression library-- would be remedial.

Additionally, the library of step (b) lacks a positive antecedent basis because there are two distinct libraries identified in step (a) as described above. To replace “the library” with --the enriched library-- would be remedial. Claim 25 is further vague and indefinite because the preamble of step (a) recites that an enriched expression library is being prepared, but the end product are cells comprising an expression library. This leads to different required steps. If preparation of an enriched library is indeed the initial goal, to recite steps where the library is isolated and then introduced to cells prior to step (b) would be remedial. **This is a new rejection necessitated by applicants’ amendment of the claims in the response filed 10/8/2004.**

12. Claim 57 is vague and indefinite because there is no basis for sorting the cells in either step (a) or step (c). To insert steps reciting insulin stimulation prior to step (a) and (c) would be remedial, unless again the sort of step (c) is only intended to enhance the purity of the sorted

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populations from step (b). In this case, it would be remedial to insert an insulin stimulation step prior to step (a) and clearly delineate that the sort of step (c) is intended for further enrichment/purity purposes. **This is a new rejection.**

### ***Double Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1, 10, 11, 15, 20, 21, 25, 30, 31, 54, and 57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23, 28, and 29 of U.S. Patent No. 6,632,924 in view of Seed (Curr. Opin. Biotechnol. 6:567-573 (1995), newly cited), as follows, instant claims 1, 15, 25, 54, and 57 over patent claim 23, instant claims 10, 20, and 30 over patent claim 28, and instant claims 11, 21, and 31 over patent claim 29. The patent claims are drawn to a method for identifying "an agent" which is involved in GLUT4 trafficking to the plasma membrane. The patent claims do not address using an expression library as the "agent" as the instant claims do. Seed teaches (whole article) the well-known process of expression cloning for the identification of new genes in a signaling pathway. The instant claims are essentially drawn to method of expression cloning for the identification of proteins involved

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in GLUT4 trafficking to the plasma membrane. As “a major attraction of expression cloning is its potential for revealing proteins of unknown sequence (and unknown physical properties) solely on the basis of a preidentified biological activity” (Seed page 567, column 1, paragraph 2), the skilled artisan would have been motivated to perform expression cloning to identify novel proteins in the process of GLUT4 trafficking to the plasma membrane utilizing expression libraries as the “agent” of the patent claims. Thus, it would have been obvious to one of ordinary skill in the art to screen an expression library as in the instant claims in the screening method of the patent claims.

### ***Conclusion***

15. Claim 55 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick S. Riggins whose telephone number is (571) 272-6102.

The examiner can normally be reached on M-F 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick Riggins, Ph.D.  
Examiner  
Art Unit 1636



**JAMES KETTER**  
**PRIMARY EXAMINER**